



## PRESS RELEASE

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### **AG Gansler: Wyeth Pays \$491 Million to Resolve Allegations it Marketed the Kidney Transplant Drug, Rapamune, for Unapproved Uses**

*Maryland to recover more than \$500,000 for Medicaid*

**Baltimore, MD ( July 31, 2013)** - Attorney General Douglas F. Gansler announced today that Maryland, in conjunction with other states and the federal government, has secured a \$491 million dollar settlement to resolve civil and criminal allegations that Wyeth Pharmaceuticals, Inc., of Collegeville, Pennsylvania, promoted the sale and use of Rapamune for uses that had not been approved by the Food and Drug Administration (FDA). Rapamune is an FDA approved kidney transplant drug which is prescribed to prevent the body from rejecting the donor organ. Maryland will recover \$517,436.00 for the state Medicaid Program, a portion of which will be returned to the federal government.

"Drug companies put profits before people when they intentionally market and sell their drugs for uses that have not been approved," said Attorney General Gansler. "The impact on patients in Maryland is greater than the amount recovered by the state, given that most of this abuse affected transplant recipients covered by Medicare and other federally funded health care programs."

The investigation resulted from qui tam actions filed in the United States District Courts for the Eastern District of Pennsylvania and the Western District of Oklahoma under the federal False Claims Act and various state false claims statutes. The complaints alleged that Wyeth knowingly promoted the sale and use of Rapamune for use with solid organ transplant patients other than kidney transplant patients and in treatment regimens with transplant patients who used another immunosuppressant drug before using Rapamune when they did not receive Rapamune at or around the time of a kidney transplant.

Wyeth has agreed to pay the states and the federal government \$257,400,000 in civil damages and penalties to resolve the civil allegations of off-label marketing of Rapamune. Over \$60 million dollars of this amount will go to the Medicaid program, which is funded jointly by the states and the federal government. The remaining \$197,266,067 is designated for other federal health care programs affected by Wyeth's conduct. Additionally, Wyeth pleaded guilty in federal court in Oklahoma to violations of the U.S. Food, Drug, and Cosmetic Act, and has agreed to pay \$233,600,000 in criminal fines and forfeitures.

In late 2009, Pfizer Inc. acquired Wyeth Pharmaceuticals, Inc. The off-label marketing, and the conduct to which Wyeth pled guilty, occurred prior to Pfizer's acquisition of Wyeth. Pfizer cooperated fully with the federal government and the states in the investigation.

A team from the National Association of Medicaid Fraud Control Units (NAMFCU) conducted the settlement negotiations with Wyeth & Pfizer on behalf of the states.

In making the announcement, Attorney General Gansler thanked Medicaid Fraud Control Unit Deputy Director Shelly Marie Martin and Chief Auditor Ruth Jarrell for their work on this matter.